#### REMARKS

### I. Summary of Office Action

Claims 1-11 and 13-27 are pending in this case.

The Examiner has withdrawn claims 2-11 pursuant to 37 C.F.R. § 1.142(b) as being drawn to a non-elected species. The Examiner has objected to the specification as failing to provide proper antecedent basis for the claimed term "sharpened." The Examiner has rejected claims 1, 13 and 18-27 under 35 U.S.C. § 102(b) as anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Taylor U.S. patent 3,952,742 (hereinafter "Taylor"). Claims 14, 16 and 17 have been rejected under 35 U.S.C. § 103(a) as obvious over Taylor. The Examiner has further rejected claim 15 under 35 U.S.C. § 102(b) as anticipated by, or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Chu et al. U.S. patent 6,176,834 (hereinafter "Chu").

### II. Summary of Applicants' Reply

Applicants have canceled claim 13 without prejudice. Applicants have amended claim 1 in order to more particularly define the invention. Support for the amendment may be found in the specification from page 17, line 11 through page 19, line 12 and also in FIG. 8. The Examiner's objections and rejections are respectfully traversed.

# III. Applicants' Reply to Examiner's Comment Regarding Admitted Prior Art

The Examiner contends in his current rejection of dependent claim 14 in the instant Office Action that since applicants failed to traverse the earlier statement made by the Examiner in the October 9, 2003 Office Action, with regard to claim 14, that "it was well known in the art to provide external threads on surgical devices," this statement is taken to be admitted prior art.

Applicants respectfully submit that, contrary to the Examiner's contention, it was moot to address this statement in the Reply to Office Action filed

March 9, 2004, because applicants instead addressed the rejections to independent claim 1, and furthermore stated that dependent claim 14 was allowable "for at least the [] reasons" that claim 1 was allowable. Accordingly, applicants request that this comment be withdrawn.

## IV. Applicants' Reply to the Prior Art Rejections

Applicants' invention, as defined by amended claim 1, is directed towards an instrument for creating an aperture through a side wall of a patient's tubular body organ structure. The instrument includes an elongated guide structure that is longitudinally insertable into the tubular body organ structure from a point of insertion to a remote point where the aperture is to be created. The

instrument also includes a longitudinal structure guided by and longitudinally movable relative to the guide structure, and has a distal portion that is adapted to penetrate the side wall. The elongated guide structure and longitudinal structure are both deflectable toward the side wall at the remote point.

Taylor is directed toward a cannula-type cardiac resuscitation instrument that consists of flexible tube 12 and rigid needle 14. The needle acts as a rigid penetration and carrying device for carrying the flexible tube into a proper position with respect to the patient's heart. Rigid needle 14 is inserted into a central axial passage of flexible tube 12, which is carried into position by the needle through the cardiac wall. After penetration of the cardiac tissue, the needle may be withdrawn to leave the flexible tube in position in order to inject medication into the patient's heart.

Chu is directed to a minimally invasive biopsy device that includes a cylindrical retractor and a cylindrical cutting tool that is slidingly engaged within the cylindrical retractor. The cylindrical retractor is inserted into an incision that is above a lesion that is to be excised, and separates the walls of the incision to provide access to the tissue to be excised. Moreover, the cylindrical cutting tool has an electrocautery tip on its

distal end that is used to make a cylindrical incision around the tissue to be excised.

The Examiner contends that the cardiac resuscitation instrument discussed in Taylor, consisting of flexible tube 12 and rigid needle 14, meets all the features of applicants' claim 1. The Examiner further states that alternatively it would have been obvious to insert flexible tube 12 into a tubular organ due to the size of the tube, and that rigid needle 14 is inherently capable of being moved relative to flexible tube 12 (Office Action, para. 3, pp. 2-3).

Applicants, however, respectfully submit that
Taylor does not show or suggest an elongated guide
structure and a longitudinal structure that are both
deflectable toward the side wall at the remote point.
Rather, needle 14 described in Taylor is preferably quite
rigid and may be made of stainless steel (Taylor, col. 2,
11. 35-36). As a result, it is not possible for such a
needle to be deflectable toward the side wall of a
patient's tubular body organ structure at the remote point
as defined by applicant's claim 1.

The Examiner further cited Chu in rejecting claim 15, stating that cylindrical cutting tool 14 and electrocautery tip 82 of the biopsy device described in Chu meet the features of the applicants' claimed elongated guide structure and longitudinal structure, and further

that the distal portion of electrocautery tip 82 is resiliently biased to deflect laterally when released from guidance by the guide structure (Office Action, para. 3, pp. 2-3).

Applicants, however, respectfully submit that Chu does not show or suggest an elongated guide structure and a longitudinal structure that are both deflectable toward the side wall at the remote point as defined by applicants' claim 1. For example, rather than describing electrocautery tip 82 as being outwardly deflectable, as would be required if the tip were deflectable toward the side wall of a tubular organ structure, Chu describes the tip as being capable of being curved inward to facilitate the excising of the biopsy tissue (Chu, col. 4, ll. 51-62 and FIG. 8). In this regard, altering the electrocautery tip to deflect outward would run counter to the principle of operation of the device in Chu.

Furthermore, Chu makes no mention that cylindrical cutting tool 14 is deflectable. In fact, both the cylindrical cutting tool 14 and the cylindrical retractor 12 are shown in FIG. 5 to be substantially rigid. Therefore, Chu also does not show or suggest an elongated guide structure that is deflectable toward the side wall at the remote point as required by applicants' claim 1.

Accordingly, for at least the foregoing reasons, applicants submit that independent claim 1 and dependent

claims 14-27 -- which depend either directly or indirectly from claim 1 -- are allowable over Taylor and Chu and respectfully request that the rejections of these claims be withdrawn.

### V. Conclusion

In view of the foregoing, applicants submit that claims 1 and 14-27 are in condition for allowance.

Reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,

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